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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,035	03/23/2004	Antonius Adrianus Hendrikus Petrus Megens	JAB-1751CON2	2709

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PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
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CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/807,035

Applicant(s)

PETRUS MEGENS, ANTONIUS  
ADRIANUS HENDRI

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's election without traverse of Group II, claims 33-37, with the species of claim 37 in the reply filed on Mar. 20, 2006 is acknowledged.

Claims 1-32 have been canceled. Claims 33-37 are pending.

2. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the scope of claim 33. Please note that the term "accelerating" is a relative term wherein a comparison with certain level of activity must be referring to. It is unclear what the meets and bounds of this term is defining since acceleration can mean faster in emptying the gut content or increased volume of fluid thus enhances cleansing etc. It is unclear that without comparison what is the scope of the claim.

3. Claims 33-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to method of "accelerating intestinal cleansing" using (+)-norcisapride and a laxative. In the specification, it was stated that (+)-norcisapride has a synergistic effect with osmotic agents (p.8) and the specification also disclosed that "Laxatives are drugs that promote defecation. Precise mechanisms of action of many laxatives remain

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uncertain....". No correlation between synergism of norcisapride and osmotic agent or any particular laxative and the *claimed* acceleration can be found. As it is understood by the term acceleration, it has to be an increase by comparison with certain non-accelerated level for which description was not found.

In addition, while a statement of synergistic effect of norcisapride and osmotic agents was made, no description on how such process was carried out with what dosage as to produce synergism. Further, the statement for norcisapride and osmotic agents, does not automatically extrapolate to *all* laxatives especially, the specification made it clear that not all laxatives are the same and different laxatives commensurate different mechanism. Therefore, the alleged synergism even if it provides acceleration for the combination of norcisapride and osmotic laxatives, does not provide description or enablement for other laxatives broadly encompassed by the term.

4. Claims 33-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to 'accelerating' intestinal cleansing using combination of norcisapride which is a prokinetic agent and a laxative. The insufficiency of descriptive support for such acceleration has been analyzed supra and hereby incorporated by reference. The field of the claimed acceleration method is recognized by artisan in the field to be requiring controlled trials for any possibility to be formulated into treatment (see Lancet cited on PTO-892). In

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absence of *any* combination supporting the alleged synergism with dosage, site of administration, sequence of administration, one skilled in the art lacks the required guidelines for operating such method. Especially, the field has been recognized to be deficient in such general knowledge.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toosen J D et al. in view of Leng-Peschlow E. and McCullough et al. US 6,147,093.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Toosen et al. disclosed bowel cleansing using laxatives, electrolyte lavage or prokinetics. An example of using combination osmotic agent and prokinetic agent was found on page 204, Table 1, PEG-electrolyte and Senna (see Senna is prokinetic agent, EMBASE 1992073425).

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the instant claims and the prior art is that the specific combination of laxative and (+)-norcisapride was not disclosed. However, it was stated that cisapride which stimulate gastrointestinal activity is a desirable combination with PEG-

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electrolyte (see p.211). McCullough et al. disclosed that norcisapride is a prokinetic agent and has activity in stimulating the motility of the gastrointestinal system (see col. 6, lines 38-45).

*Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)*

One having ordinary skill in the art in possession of the above reference would be motivated to employ an combination of osmotic agent together with prokinetic agent (+)Norcisapride **because** combination of agents is recommended for a cleansing regimen. The use of an alternative prokinetic instead of the exemplified prokinetic is choosing some among many indiscriminatively, thus, prima facie. In re Lemen 141 USPQ 814.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. SciSearch 03168042 in view of McCullough et al. US 6,147,093 and Garattini et al.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Ueda et al. disclosed combination colonoscopy cleansing with osmotic agent and cisapride (see whole article).

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the instant claims and the prior art is that instead of cisapride, the instant claims employed a cisapride metabolite (see McCullough '093, col. 4, line 48-vol. 5, line 19), and has less side effects known to cisapride (see col. 8, lines 45-48). Garattini et al. taught that, an active metabolite of a drug is contributing to the duration of action of the parent drug (see section 3, p. 219).

*Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)*

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One having ordinary skill in the art in possession of the above references will be motivated to modify the Ueda et al. method of colono-cleansing by employing the cisapride metabolite instead of cisapride knowing that the combination gave shortened preparation time and knowing that the metabolite is active and has contributed to the process, knowing that the metabolite is devoid of undesirable side effects than cisapride. One has been guided with the proper dosage (as taught in the conversion rate col. 4, line 48-col. 5 line 19), the expected low side effect (col. 8, lines 45-48), and the operability in stimulating motility of the gastrointestinal tract (col. 10, lines 20-23, col. 6 lines 38-42). It is prima facie obvious to replace an agent in a combination treatment with an analogous agent known to operate in similar manner with less side effect.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Jun 22, 2006

  
Celia Chang  
Primary Examiner  
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